


CERASORB®	Section 05
510(k) Summary	RIEMSER  Arzneimittel AG

Special 510 (k) Summary:
CERASORB® CLASSIC
CERASORB® M
CERASORB® Perio

SEP 20 2012

Date prepared: September 17, 2012

1. SUBMISSION INFORMATION

Name and Address of the Sponsor: Riemser Arzneimittel AG
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2. DEVICE IDENTIFICATION

Proprietary Name: CERASORB® CLASSIC
CERASORB® M
CERASORB® Perio


Common Name: Bone Void Filler, Synthetic

Classification Name: Bone Grafting Material, Synthetic

Classification: Class II, Special Controls

Classification regulation Number: 21CFR 872.3930

Product Code: LYC

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3. PREDICATE DEVICES

CERASORB® DENTAL: k051443
CERASORB® M DENTAL: k051443
CERASORB® Perio: k051443

4. INTENDED USE

CERASORB® CLASSIC and CERASORB® M are recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of the maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of perio-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

CERASORB® Perio is recommended for:


- Filling and/or reconstruction of non-infected periodontal bone defects in conjunction with other products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of infrabony periodontal defects
- Filling of single-or multi-wall bone pockets
- Filling of bifurcations and trifurcations

5. DESCRIPTION OF THE DEVICE

CERASORB® CLASSIC, CERASORB® M and CERASORB® Perio are a sterile, synthetic, porous and biocompatible ceramic matrix in either granular form (CERASORB® CLASSIC), polygonal shaped morsels (CERASORB® M) or polygonal broken granulate (CERASORB® Perio). All designs consist of pure-phase Beta-Tricalcium Phosphate with a phase purity of $\geq 99\%$ and comply with the ASTM F 1088-04. The devices, when applied to a bony defect, create a network of large, smoothly interconnected pores providing different porosities (CERASORB® CLASSIC approx. 35%, CERASORB® M approx. 65 vol% [total porosity] and CERASORB® Perio approx. 25vol%).

The different designs are manufactured by a validated manufacturing process which guarantees batch to batch conformity and reproducibility.

In contact with vital bone the CERASORB® granules, morsels or granulate is resorbed and gradually replaced by new bone.

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CERASORB® CLASSIC, CERASORB® M and CERASORB® Perio are provided in double sterile packages (sterilization via gamma irradiation) and are for single-use only.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

CERASORB® CLASSIC, CERASORB® M and CERASORB® Perio differ from the products of the same name cleared by k051443 only in the information on the labeling designating the manufacturer. Riemser AG is now both the manufacturer and distributor of the CERASORB® products described in the present 510(k) document.

7. STATEMENT OF TECHNOLOGICAL COMPARISON

The CERASORB® CLASSIC, CERASORB® M, and CERASORB® Perio devices are substantially equivalent to the respective devices cleared by k051443: CERASORB® DENTAL, CERASORB® M Dental, and CERASORB® Perio.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

SEP 20 2012

Riemser Arzneimittel AG
C/O Mr. James M. Clinton
Quality & Regulatory Consulting, Limited Liability Company
5105 Fair Oaks Road
Durham, North Carolina 27712

Re: K113282

Trade/Device Name: Cerasorb® Classic
Cerasorb® M
Cerasorb® Perio

Regulation Number: 21 CFR 872.3930

Regulation Name: Bone Grafting Material

Regulatory Class: II

Product Code: LYC

Dated: August 17, 2012

Received: August 21, 2012

Dear Mr. Clinton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices


Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K113282

CERASORB®	Section 04
Indications for Use	RIEMSER  <small>Argon-filled 40</small>

Indications for Use

510(k) Number (if known): K113282

Device Name: Cerasorb® CLASSIC

Indications for Use:

Cerasorb® CLASSIC is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of perio-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

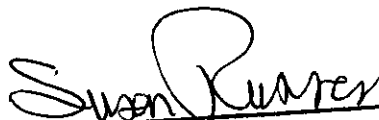
Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)




(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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CERASORB®	Section 04
Indications for Use	RIEMSER 

Indications for Use

510(k) Number (if known):

Device Name: Cerasorb® M

Indications for Use:

Cerasorb® M is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

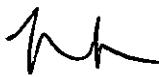
Prescription Use ☒
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
 (21 CFR 807 Subpart C)

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CERASORB®	Section 04
Indications for Use	 <small>Arbeitsmittel AG</small>

Indications for Use

510(k) Number (if known):

Device Name: Cerasorb® Perio

Indications for Use:

Cerasorb® Perio is recommended for:

- Filling and/or reconstruction of non-infected periodontal bone defects in conjunction with other products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of infrabony periodontal defects
- Filling of single-or multi-wall bone pockets.
- Filling of bifurcations and trifurcations

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

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